

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

CAVALERI et al.

Serial No.: Not yet assigned

Filed: Submitted herewith

For: STABLE PHARMACEUTICAL
COMPOSITIONS OF
DALBAVANCIN AND METHODS
OF ADMINISTRATION

Group Art Unit: Not yet assigned

INFORMATION DISCLOSURE STATEMENT

MAIL STOP PATENT APPLICATION

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97–1.98, information relating to the above-identified application is hereby disclosed. The accompanying Form PTO–1449 provides a listing of documents that may be relevant to the subject application.

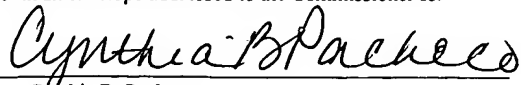
It is requested that the Examiner fully consider the art cited in the accompanying Form 1449, initial the left-most column of the form adjacent each cited reference, and return a copy for Applicants' records. It is further requested that the art be cited on the cover of any patent issuing from the subject application.

CERTIFICATE OF MAILING (37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Commissioner for Patents, PO Box 1450 Alexandria, VA 22313-1450.

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April 16, 2004
Date of Deposit


Cynthia B. Pacheco

In accordance with §1.97(b), this Information Disclosure Statement is being filed within three months of the filing date of the above-identified application, and therefore no fee is required.

In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the Patent and Trademark Office in one or more of the prior U.S. Application Serial No. 10/714,261, filed November 14, 2003, which claims the benefit of U.S. Provisional Patent Application Serial Nos. 60/427,654, filed November 18, 2002, 60/485,694, filed July 8, 2003, 60/495,048, filed August 13, 2003, and 60/496,483, filed August 19, 2003, by CAVALERI, et al. for which a claim for priority under 35 U.S.C. §120 has been made in the instant application. Accordingly, Applicants will provide duplicate copies in respect of the present case only if the Examiner so desires.

This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made. Nor does this statement constitute an admission by Applicants or Applicants' agent that the information provided herein is necessarily prior art to Applicants' invention. Moreover, Applicants reserve the right to establish the patentability of the claimed invention over any of the listed documents should they be applied there-against as references. Please charge any deficiency or credit any overpayment to Deposit Account No. 50-2862.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: April 16, 2004

By *Diane K. Wong*
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Form PTO-1449

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)

Docket No. 892,280-

Application No.: Not Yet Assigned

Applicant: CAVALERI et al.

Filing Date: Submitted herewith

Group Art Unit: Not Yet Assigned

Mailing Date: April 16, 2004

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	03/25/1980	4,195,079	Celmer et al.			
	2.	12/16/1980	4,239,751	Coronelli et al.			
	3.	09/17/1985	4,542,018	Borghi et al.			
	4.	04/28/1987	4,661,470	Malabarba et al.			
	5.	11/01/1988	4,782,042	Selva et al.			
	6.	09/19/1989	4,868,171	Selva et al.			
	7.	11/21/1989	4,882,313	Sitrin			
	8.	04/03/1990	4,914,187	Malabarba et al.			
	9.	06/19/1990	4,935,238	Selva et al.			
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	18.	07/20/1999	5,925,550	Lancini et al.			
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	21.	11/07/2000	6,143,739	Lociuro et al.			
	22.	04/17/2001	6,218,505	Panzone et al.			
	23.	05/07/2002	6,384,013	Burkhardt et al.			

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FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO	
	24.	02/16/1983	EP 0 071 970	Europe				
	25.	11/30/1983	EP 0 095 154	Europe				
	26.	04/16/1986	EP 0 177 882	Europe				
	27.	12/10/1986	EP 0 204 179	Europe				
	28.	07/08/1987	EP 0 228 015	Europe				
	29.	10/14/1987	EP 0 240 609	Europe				
	30.	03/16/1988	EP 0 259 781	Europe				
	31.	02/01/1989	EP 0 301 785	Europe				
	32.	05/24/1989	EP 0 316 712	Europe				
	33.	07/04/1990	EP 0 376 041	Europe				
	34.	02/03/1993	EP 0 525 499	Europe				
	35.	10/15/1997	EP 0 801 075	Europe				
	36.	07/28/1999	EP 0 931 834	Europe				
	37.	12/21/1983	GB 2 121 401	Great Britain				
	38.	02/15/1984	GB 2 142 234	Great Britain				
	39.	02/01/1989	JP 1050900	Japan			Abstract	
	40.	04/21/1988	WO 88/02755	WIPO				
	41.	10/04/1990	WO 90/11300	WIPO				

OTHER DOCUMENTS

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Examiner Initials	Ref. No.	Title
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	43.	Adamczyk, M. et al. (1999). "Investigations Into Self-Association of Vancomycin Covalent Dimers Using Surface Plasmon Resonance Technology," <i>Bioorganic & Medicinal Chemistry Letters</i> 9:2437-2440.

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	46.	Anderegg, T.R. et al. (2003). "Initial Quality Control Evaluations for Susceptibility Testing of Dalbavancin (BI397), an Investigational Glycopeptide with Potent Gram-Positive Activity," <i>J. Clin. Microbiol.</i> 41(6): 2795-2796.
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	53.	Author unknown. (2000). "Molecule of the Month V-Glycopeptide," located at < http://www.prous.com/mom/nov_00/mom.html > last visited on August 27, 2002, two pages.
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PTO/SB/ 08 (2-92)

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62.		Chaix, C. et al. (1999). "Control of Endemic Methicillin-Resistant <i>Staphylococcus Aureus</i> ," <i>JAMA</i> 282(18):1745-1751.
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67.		Dowell, J. et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment," <i>ECCMID: Clinical Microbiology and Infection</i> , Abstract No. P1224. Vol. 9(Supp. 1), p. 291.
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69.		Dowell, J.A. et al. (2002). "The Pharmacokinetics and Renal Excretion of Dalbavancin in Healthy Subjects," <i>42 ICAAC Abstracts</i> , San Diego, CA, September 27-30, 2002. Abstract No. A-1386, pg. - 18.
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81.	Goldstein, D. and Halsey, K. (May 21, 2002). "Versicor Announces Completion of Phase II Study of Once-Weekly Dalbavancin for Skin and Soft Tissue Infections." Press Release, three pages.
82.	Goldstein, D. et al. (May 22, 2001). "Versicor Begins Phase II Trial of Dalbavancin, Its Noval Glycopeptide Antibiotic." Press Release, three pages.
83.	Goldstein, D. et al. (December 17, 2001). "Versicor Announces Positive Phase I Data for Dalbavancin, Demonstrating Feasibility of Once-Weekly Dosing." Press Release, four pages.
84.	Goldstein, D. et al. (September 5, 2002). "Versicor Announces Positive Phase 2 Study Results With Dalbavancin For Skin and Soft Tissue Infections." Press Release, three pages.
85.	Goldstein, D. et al. (September 19, 2002). "Versicor Announces 24 Abstracts to be Presented at Annual ICAAC Meeting Next Week." Press Release, three pages.
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91.	Griffin, J.H. (2003). "Multivalent Drug Design, Synthesis and In Vitro Analysis of an Array of Vancomycin Dimers," <i>JACS</i> 125:6517-6531.
92.	Hackbarth, C.J. et al. (1999). "In Vitro Activity of the Glycopeptide BI 397 Against <i>Staphylococcus aureus</i> and <i>Staphylococcus epidermidis</i> ," <i>39th Annual ICAAC</i> , San Francisco, CA. September 1999. Abstract No. 1283, pg. 332.
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	103.	Jabes, D. et al. (2003). "Efficacy of Dalbavancin Compared with Vancomycin and Linezolid in the Rat Granuloma Pouch Model of Staphylococcal Infection," <i>Symposium on Surgical Infections</i> , Como, Italy Poster No. P1 , one page.
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